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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,125	08/14/2001	Susan Hand-Zimmermann	210121.544	9404

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,125	HAND-ZIMMERMANN ET AL	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-5 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2-5 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed December 8, 2003 in response to the Office Action of August 8, 2003 is acknowledged and has been entered. Previously pending claims 1 and 6-12 have been cancelled, claims 2-3 have been amended and new claim 13 has been added. Claims 2-5 and 13 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

3. Claims 2-5 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of an isolated polypeptide comprising SEQ ID NO:3 and consisting of no more than amino acid residues 975-1209 of human Her-2/neu has no clear support in the specification and the claims as originally filed. Applicant points to page 87, lines 7-25 of the specification for support for the newly added limitation. The support has been considered but has not been found persuasive because a review of page 87 lines 7-28 reveals support for an epitope contained within the 235 amino acid fragment beginning at position 975 in the Her-2/neu sequence wherein the epitope was found in positions 1021-1030, designated as SEQ ID NO:3. Addition of 235 amino acids to position 975 reveals that the fragment described consists of amino acid 975 through 1209. The cited support is supportive for a fragment consisting of 235 amino acids from amino acid 975 through 1209 of SEQ ID NO:2, but is not supportive of the broadly claimed fragments of the 235 amino acid fragment consisting of 10 through 235 amino acids, including the residues of SEQ ID NO:3, within the range of amino acids as currently claimed. The specification neither contemplates nor suggests these

specific fragments. The subject matter claimed in claims 2-5 broadens the scope of the invention as originally disclosed in the specification.

Claim Rejections - 35 USC § 103

4. Claims 2-5, 13 are rejected under 35 U.S.C. § 103 as being unpatentable over US 2002/0177567 in view of Harlow and Lane, of record, Johnstone and Thorpe, of record.

The claims are drawn to an isolated polypeptide composition effective for eliciting an immune response, said polypeptide comprising the naturally processed epitope of SEQ ID NO:3 and consisting of no more than amino acid residues 975-1209 of human Her-2/neu,, a pharmaceutical composition comprising said polypeptide in combination with a pharmaceutically acceptable carrier, further comprising an immunostimulant, an adjuvant, said polypeptide consisting essentially of SEQ ID NO:3..

US 2002/0177567 teaches a 59 amino acid fragment of human Her-2/neu, SEQ ID NO:5 which has 100% identity to a portion of SEQ ID NO:2 within the range of amino acids 975-1209 (see col. 41 and see us-09-930-125-2, rapb result attached hereto), which comprises SEQ ID NO:3 (see us-09-930-125-3 rapb result 3, attached hereto) wherein the polypeptide consists essentially of SEQ ID NO:3. The reference further teaches that SEQ ID NO:5 is a fragment of the phosphorylation domain and a preferred portion of human HER-2/neu. The reference further teaches that the phosphorylation domain of human HER-2/neu shares no identity with the corresponding part of other tyrosine kinases receptors. The specificity and uniqueness of this domain makes it particularly preferred for use as a tumor vaccine, (p. 6, para

0066). The reference teaches as set forth above, but does not teach a composition comprising said polypeptide in combination with a pharmaceutically acceptable carrier, said composition further comprising an immunostimulant, wherein said immunostimulant comprises an adjuvant.

Harlow and Lane teach that adjuvants are essential to strong antibody response to soluble antigens (p. 9, para 1). The overall effect of adjuvants is dramatic and their importance cannot be overemphasized. A much smaller dose of antigen can be used and antibody responses are more persistent. The nonspecific activation of the immune response often can spell the difference between success and failure in obtaining an immune response. Adjuvants should always be used for the first injection unless there is some very specific reason to avoid this.

Johnstone and Thorpe teach that it was common practice in the art at the time of appliant's invention to formulate compositions of protein and PBS, which is considered to be a pharmaeutically aceptable carrier.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, and one would have been motivated, to have made a pharmaceutical composition comprising the polypeptide of SEQ ID NO:5 of US 2002/0177567 comprising a pharmaceutically acceptable carrier, an immunostimulant, an adjuvant because US 2002/0177567 specifically teaches that SEQ ID NO:5 is a fragment of the phosphorylation domain and a preferred portion of human HER-2/neu. The reference further teaches that the phosphorylation domain of human HER-2/neu shares no identity with the corresponding part of other tyrosine kinases receptors and the specificity and uniqueness of this domain makes it particularly preferred for use as

a tumor vaccine. Since the manufacture of a vaccine conventionally requires administration of the antigen to an animal in a pharmaceutical composition, a pharmaceutical composition comprising said antigen is *prima facie* obvious, especially in view of the teachings of Johnstone and Thorpe who teach that it was common practice in art at the time of applicant's invention to formulate compositions of proteins and PBS, which is considered to be a pharmaceutically acceptable carrier. In addition it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, and one would have been motivated, to include adjuvant in the composition because Harlow and Lane teach that adjuvants are essentail to induce a strong antibody response to soluble antigens. The overall effect of adjuvants ids dramatic and their importance cannot be overemphasized. A much smaller dose of antigen can be used and antibody responses are more persistent. The nonspecific activation of the immune resposne often can spell the difference between success and failure in obtaining an immune response.

5. All other objections and rejections recited in Paper mailed August 8, 2003 are withdrawn.

6. No claims allowed.

7. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO

MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871. The fax phone number for this Art Unit is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
February 12, 2003